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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/809,956 | 03/26/2004 | Matthew J. Dejneka | SP04-025 | 7898 |

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| EXAMINER | |
|---|---|
| LEVKOVICH, NATALIA A | |
| **ART UNIT** | **PAPER NUMBER** |
| 1743 | |

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/809,956 | DEJNEKA ET AL. | |
| | Examiner | Art Unit | |
| | Natalia Levkovich | 1743 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *21 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-4,6-10,12-14 and 16-23* is/are pending in the application.

4a) Of the above claim(s) *17-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-10,12-14,16 and 21-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03/26/2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/21/2006 has been entered.

### *Drawings*

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the porous reaction chamber having 'substantially hexagonal holes', as recited in claim 4, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet,

and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-4, 5-10, 12-14,16 and 21-23 are rejected under 35 U.S.C. 112, second paragraph, as being unclear for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The amended claim 1 does not sufficiently and clearly set forth structural cooperation between the elements. It is unclear, for example, what part of the transparent capillary constitutes the 'analysis zone', how the filter, 'integrated with the transparent capillary', is related to the zone, and what arrangement of the filter holes would provide the recited trapping the particles in the analysis zone. The same considerations refer to claim 14.

Claim 2 recites the filter extending 'laterally across the analysis zone'. This is unclear the shape of the filter, as well as the shape of the zone, are not defined in the claim.

In reference to claim 7, the transparent capillary comprising 'at least one rectangular tube', is confusing, since only one transparent capillary is recited.

As to claim 13, the structural inter-relations between the manipulation system and the positively claimed single microfluidic reactor, are not set forth in the claim.

Claim 23 recites the transparent capillary being 'dimensioned as to form a monolayer of trapped particles wherein the trapped particles are aligned in a serial fashion'. The claim is narrative in form and replete with indefinite and functional or operational language. It is not clear what structural features would provide for the recited functionality.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-3, 6-9,12,14, 16 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scrivens et al. (US 20030202908) in view of Swedberg (US 5085756) and further in view of Taniguchi et al. (US 6495041).

Scrivens discloses an apparatus for obtaining increased particle concentration for optical examination (Abstract). The apparatus includes a partially transparent sample chamber [transparent capillary' – Ex.] formed by walls 1 and lid (not shown) and having a sample entrance 3 ['flow inlet' – Ex.], separation wall 2 ['filter' – Ex.] 'laterally extending across' the chamber and having a "multiplicity of channels ['capillary tubes' – Ex.] aligned substantially parallel to each other and which traverse a separating wall between the two compartments". The separation channels are "sized to allow only particles smaller than a certain size to pass" (see [0023]).

Scrivens does not teach the chamber to be entirely transparent, however, transparent tubes made of chemically resistant materials (glass or polymers) are commonly used as reaction / analysis chambers. For example, Swedberg discloses a transparent capillary tube 18 used "to provide sample pre-treatment in situ" and having inlet and porous filter (Abstract). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have employed such entirely transparent capillary as a reaction chamber in the modified apparatus of Scrivens, in order to provide betterconditions for optical observations.

Although Scrivens does disclose the separation wall / 'filter' to have channels of capillary sizes, the reference does not teach the filter being formed of capillary tubes. However, such filters are well known in the art. For example, Taniguchi discloses a filter formed of hollow fibers 24 (Figure 3). It would have been clearly within the ordinary skill of an artisan at the time the invention was made to have employed a filter formed of capillary tubes in the modified apparatus of Scrivens, in order to increase the rate and selectivity of the particle concentrating process.

With respect to claims 12 and 23, Scrivens does not teach the capillary to be smaller than 'twice the smallest dimension of the particle being trapped', or to be dimensioned to 'form a monolayer of particles ...in a serial fashion'. The diameter of the capillary is a result effective variable. The Court decided *In Re Boesch* (205 USPQ 215) that optimization of a result effective variable is ordinarily within the skill of the art. A result effective variable is one that has predictable and well-known characteristics. The choice of a capillary diameter would result (with certain level of predictability, depending on the type of particle size distribution within a nominal range) in trapping particles of predetermined sizes (with more narrow size distribution). Provided the capillary has a constant diameter along its length, the trapped particles would form a 'monolayer', as claimed. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have optimized the capillary diameter in the modified devices of Scrivens, in order to trap the particle of certain sizes, with better size distribution. Examiner also notes that, since the particles are not positively claimed,

they are not considered to be a part of the invention and, therefore, they are not accorded any patentable weight.

With respect to claim 16, Scrivens does not the detector to be a CCD, however, these devices are notoriously well known. It would have been within an ordinary skill in the art to have employed CCD in the modified apparatus of Scrivens , since CCD are easy to operate and efficient.

Referring to claim 21, Scrivens does not teach filter to comprise microstructured fibers. However, such fibers are well known in the art (for example, in nano-technology). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have employed these fibers in the modified devices of Scrivens, in order to trap the particle of ultra small sizes.

As to claim 22, although Scrivens does not teach fusing the filter to the walls of capillary, it would have been within an ordinary skill in the art to have fused the filter to the walls in the modified devices of Scrivens, in order to attach the filter in more reliable manner.

8. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Scrivens in view of Swedberg and Taniguchi, and further in view of Chu et al. (US 5985164).

Scrivens modified by Swedberg and Taniguchi, does not disclose filter holes having hexagonal shape. However, filters / frits with hexagonal holes are well known in the art (see, for example, column 7, line 40 of the Chu reference). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have employed such filters in the modified apparatus of Scrivens, since the hexagonal shape

provides higher density of holes and forms reinforcement ribs increasing the mechanical strength in the vertical direction of the filtering unit.

9. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Scrivens in view of Swedberg and Taniguchi, and further in view of Cole et al. (US 5879949).

Scrivens, modified by Swedberg and Taniguchi, does not disclose a solvent resistant coating of transparent capillary. However, protective coatings are routinely employed in the art. For example, Cole discloses "a polyimide coating on fused silica capillary...resistant to all solvents (Col.9, line 5). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have employed a capillary tube with a solvent resistant coating in the modified apparatus of Scrivens, in order to provide the surface inert to aggressive fluids.

10. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Scrivens in view of Swedberg and Taniguchi, and further in view of Roach et al. (US 20010005489).

Scrivens modified by Swedberg and Taniguchi, does not disclose the 'manipulation system for moving microfluidic reactors', however, automatic systems handling microplates or microfluidic circuits are commonly used in the art (see, for example, [0051] and [0147] in the Roach reference).It would have been obvious to one of ordinary skill in the art at the time the invention was made to have employed a robotic arm in the modified apparatus of Scrivens, in order to provide automatic handling of the microfluidic reactors.

### *Response to Arguments*

11. Applicant's arguments dated 08/21/2006 have been fully considered but they are moot in view of new grounds of rejection.

### *Conclusion*

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalia Levkovich whose telephone number is 571-272-2462. The examiner can normally be reached on Mon-Fri, 8 a.m.-4p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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